

## REMARKS

The applicants have studied the Office Action dated February 13, 2002, and have made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 1-146 are pending, claims 1, 11, 35, 44, 47, 51-55, 65 and 73 have been amended, and new claims 74-146 have been added. Reconsideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

### Remarks Regarding the Interview:

The applicants wish to thank the Examiner and her Primary Examiner for their time in the April 5, 2002 interview with the applicant's representatives (a copy of the Examiner's Interview Summary is attached to this response). The discussions were helpful and are believed to have moved the case towards allowance. The applicants have amended the claims and have provided the following remarks in accordance with the discussions with the Examiners. The Examiners indicated that amendments along the lines of the above would generally overcome the cited prior art and the rejections as applied to claims 11-34, and would probably overcome the prior art for claims 1-10 with some additional minor amendments (which the applicants have made by adding new dependent claim 146). Thus, the application and claims 11-34 should now be in condition for allowance, and claims 1-10 are likely allowable (or definitely allowable with the minor amendments recited in claim 146). The applicants are pleased with this progress in the case and the allowability of these claims.

However, in subsequent telephone interviews, it became apparent that the Examiner is unwilling to allow the entire application, despite the offer and willingness of the applicants to make similar amendments to all of the other remaining claims. This is disappointing given the effort expended by both the applicants and the Examiners. The applicants must respectfully protect their rights, and thus they have made amendments corresponding to those made in claims 1 and 11 to the other independent claims. It is hoped that upon review of the applicant's amendments and the remarks below that the Examiners will change their position and allow the

entire application and claims. Unfortunately, it is respectfully submitted that due to business concerns, if the entire case is not allowed after this review, the applicants will likely be forced to file an appeal on any rejected claims.

In the hope of avoiding a further rejection, or an appeal, and to facilitate the Examiners' review, the applicants respectfully submit the following remarks and thoughts regarding the applicants perceptions and views of the Examiner's basis for rejecting the claims. Should the Examiner have any questions or would like to discuss any of the amendments or remarks, the Examiner is invited to call any of the undersigned representatives.

Initially, the applicants have concerns and believe that the Examiner is engaging in impermissible hindsight reconstruction of the claimed embodiments of the invention. The Examiner appears to be using the claims as a template to piece together portions of prior art references and relying on mere inferences and a stretching of the teachings to show that the claimed invention is met by the prior art. The Examiner is consistently alleging that things are inherent without any teaching or motivation for the Examiner's construction of the references. Thus, the Examiner is inadvertently falling victim to hindsight reconstruction and finding ways to avoid allowing claims that are clearly patentable.

This is contrary to the fundamental teachings of the patent law. For instance, it is the burden of the Examiner to establish why one having ordinary skill in the art would have been led to the claimed invention by the express teachings or suggestions found in the prior art or the implications in such teachings or suggestions. In re Sernaker, 217 U.S.P.Q. 1, 6 (Fed. Cir. 1983). Moreover, the Federal circuit has stated that "[i]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that 'one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'" In re Fritch, 23 U.S.P.Q.2d 1780, 1784 (Fed. Circ. 1992). "[R]ejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the

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prior art to defeat patentability of the claimed invention. Such an approach would be ‘an illogical and inappropriate process by which to determine patentability.’” In re Rouffet, 149 F.3d 1350 1357, 47 USPQ2d 1453 1457 (Fed. Cir. 1998). “To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is the use of the invention as a template for its own reconstruction -- an illogical and inappropriate process by which to determine patentability.” Sensonics, Inc. v. Aerosonic Corp., 81 F.3d 1566,1570, 38 USPQ2d 1551, 1554 (Fed Cir. 1996). The U.S. Patent Office is “obligated to consider all the evidence of the properties of the claimed invention as a whole, compared with those of the prior art. In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed Cir. 1990).

An example justifying the applicants’ concern and proposition that hindsight is being used occurred during the last telephone interview. At that time, the Examiner expressed a desire for the applicants to include a “wireless” limitation into independent claim 1, even after the applicants proposed amendments to the claims would have clearly overcome the cited art of record. The Examiner based this request on a newly identified piece of prior art that the Examiner believed would anticipate the claims. The title or patent number of the reference was not disclosed by the Examiner during the interview, but the reference was described as an external infusion pump that is carried around in a big bag (or “pouch”) attached to a harness. The Examiner also indicated that the reference showed a wired keyboard connected to the pump for programming and controlling the pump. The Examiner did admit that this infusion pump is clearly much larger and cumbersome than the claimed external infusion device, however the Examiner focused on the fact that this keyboard would be considered a remote programmer that is capable of generating the remote commands recited in the claims.

Of course, the applicants have not yet seen this prior art, but from the Examiner’s description it appears that the Examiner is reaching to fit a prior art reference to some of the elements in the claims using hindsight. In the discussions, the Examiner appeared to ignore key elements of the claims when describing the reference and seemed unwilling to reconsider these key elements in the Examiner’s analysis. For instance, claim 1 recites “the housing is sized to fit in a clothing pocket.” But it is hard to understand how the described bag structure, which was

admitted by the Examiner to be much larger than the claimed embodiment, could be sized to fit in a clothing pocket, as recited in claim 1. The Examiner also stated that the keyboard is a remote programmer for producing “remotely generated commands,” as recited in claim 1. However, the applicants wonder, if the keyboard is required for all programming and is permanently attached, how can it be a remote programmer? It is respectfully submitted that one of ordinary skill in the art would consider this wired keyboard as part of the infusion pump and not as a remote programmer. Claim 1 further recites that “the external infusion device is capable of being concealed from view on an individual when being remotely commanded.” If the infusion device in the reference is a large pump in a bag, how can it be concealed? The Examiner has repeatedly argued that one can put large enough clothes on anyone and then conceal the pump. However, the applicants respectfully submit that it is a stretch to suggest that one of ordinary skill in the art would essentially wrap an individual with a tent-like layer of fabric, hide a large and heavy pump under this fabric, and also argue that the pump is concealed from view. In addition, the Examiner has not explained how, even it were found to be concealed, the large pump could be commanded when concealed, since the attached keyboard (with a clearly visible wire) would need to be visible during the programming of the large pump.

Moreover, the Examiner did not provide any support at the time to show why the reference would teach or motivate one of ordinary skill in the art to modify or convert a large infusion pump that is designed for programming with an attached keyboard to a remotely commandable external infusion device that can be remotely programmed while concealed from view on a user and that has a housing sized to fit in a clothing pocket, as recited in the claims. It is hoped that, should the Examiner maintain the position that this possible new reference anticipates the claims, the Examiner will point to specific sections of the new reference to show exactly how it meets each and every limitation of the claims, or, in the alternative, to support in the reference that shows why one of ordinary skill in the art would be taught or motivated to meet the claim limitations.

As to other matters raised during the interview, the Examiners requested that the applicants include more structure in the claim for a drive mechanism to infuse the liquid. Since

the limitation does not unduly limit the claim, all of the pending independent claims have been amended to recite "a drive mechanism to operatively couple with a reservoir to infuse a liquid into a body." Support for this amendment may be found in Figs. 1 and 2 and page 9, line 21 to page 10, line 14 of the instant application. It is respectfully submitted that this amendment is being made for formalities and not for reasons of patentability.

Also during the interview, the prior art of record was discussed and the Examiners indicated that some structural features related to the housing of the external infusion device would overcome the prior art of record if included in the body of the claim. Follow-up telephone interviews were conducted on proposed claim amendments. And now all of the independent claims have been amended to recite "the housing is sized to contain at least a portion of a reservoir, wherein the drive mechanism is contained within the housing, wherein the drive mechanism operatively couples with the at least a portion of a reservoir within the housing, and wherein the housing is sized to fit in a clothing pocket." Support for these amendments may be found in Figs. 1 and 2, and page 1, page 9, line 21 to page 10, line 14 and page 12 of the instant application. Although a specific discussion of how the amendments overcome the current rejections will be handled below, the claims, as amended, now more clearly cover all external infusion devices that include drive mechanisms and at least a portion of the reservoir within the housing when used, and are sized to fit a clothing pocket, while avoiding hospital type devices that are mounted on IV poles and are not adapted to be worn on a body of a patient. Accordingly, it is respectfully submitted all of the pending claims should now be in condition for allowance.

In addition, the applicants have added several new dependent claims (74-145) for each pending independent claim to further clarify the limitation of "sized to fit in a clothing pocket." The purpose is to show that the external infusion device is sized to fit in a pocket, but does not need to be in a pocket to operate or be used. Also, the limitations on the housing, added to the independent claims, should not be read as to exclude external infusion devices that utilize needles, tubes, catheters, cannulas, infusion sets, and/or the like to deliver a liquid to a body, or that can be worn on belts, under clothing, or against or on the skin of a patient.

Remarks in Response to Potential Restriction:

During the interview, the Examiner raised the possibility of issuing a restriction on claim 35 for the first time. The Examiner has never previously raised this issue before, and it came as a surprise that the possibility of a restriction is being only raised now. The applicants do not believe a restriction is proper or necessary, and that a restriction now would unjustly penalize the applicants. Accordingly, the applicants respectfully request the Examiner to reconsider this position for several reasons.

First, a restriction at this time is likely improper, since this application has already had three Office Actions (including a final Office Action and an RCE) on the merits for all claims. It is noted that under 37 C.F.R. § 1.142, a restriction “may be made at any time before [a] final action” in the case – this has occurred. This application has already had a final Office Action and an Office Action after and RCE. Accordingly, a restriction of any the claims at this point would be improper under 37 C.F.R. § 1.142.

Second, under MPEP 803 a restriction is improper or unnecessary “[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.” This has been done - the Examiner has already searched all of the claims at least 3 times. Each of the previous Office Actions were very detailed (e.g., two of these actions were each over 13 pages) and specifically addressed all the key elements in all of the different independent claims. Thus, there is a large amount of prosecution history (involving 10 different references) already in the file on all of these claims. Accordingly, the Examiner has searched and examined all of the claims in this case at least three times, the applicants responded more than three times, and the Examiner has never previously raised any issue that would require restriction. Accordingly, restriction of any the claims at this point would be improper and/or unnecessary under MPEP 803.

Third, the applicants respectfully point out that this case has been pending since June 16, 1999 (claiming priority to August 18, 1998), or almost three years. As discussed there have been

three Office Actions (involving 10 different references) with very detailed and specific rejections directed to all of the claims. In addition, the applicants in the two previous Office Actions overcame all of the rejections with consistent amendments to all of the independent claims. To require a restriction at this stage (even if it were proper), would unfairly penalize the applicants in multiple ways. For instance, if divisional applications are required, the applicant will suffer significant delays in obtaining a patent and a consummate reduction in patent term – now likely to be less than 17 years. Also, there is no term extension possible on the divided out claims, even though the delay would be due to the Patent Office's delay in issuing a restriction, since the patent term is not extendable for filing a divisional or continuation. This would be unfair, since if a timely (and assumed to be proper) restriction had been made, the applicants would likely have already filed divisional applications and would be well along in prosecution. Accordingly, restriction of any the claims at this point would result in significant term reductions without the possibility of obtaining a term extension, which would penalize the applicants through no fault of their own.

Finally, the applicants have spent considerable time educating the Examiner and the Primary Examiner in this case, both by the previous three Office Action responses and in interviews (both telephonic and in person). If a divisional is filed, there is no guarantee that the same Examiner would handle the case, and the applicants might experience new delays as the new Examiners learn this case.

Applicants believe strongly that a restriction at this time is improper, unnecessary and would unfairly penalize their rights. Due to the importance of this case, maintenance of a restriction requirement on claim 35, or any claim, will likely necessitate the applicants filing an appeal to the Board or a petition to the Director. Therefore, the applicants respectfully request the Examiner to reconsider and decide not to issue a restriction of claim 35, or any other claims, in this case.

Remarks in Response to Rejections in the Outstanding February 13, 2002 Office Action:

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The applicants will now address how the new limitations in the independent claims overcome the prior art of record in this case. In addition, to protect their rights in further applications or actions, due to the extremely detailed nature of the Examiner's rejections, the applicants must also respectfully respond to and point out any other patentable differences between the claims, the cited art and the Examiner's remarks made in the instant Office Action. The applicants will specifically point out where the applicants disagree with the Examiner's interpretation of the references, even though this is not needed to overcome the rejections of the independent claims in view of the new amendments. If the Examiner disagrees with the applicants remarks, the Examiner is requested to quote the language in the reference and to then specifically explain and point out why the Examiner's position is correct.

This is not being done to burden the Examiner. But must be done to avoid having applicants' silence on each of the Examiner's statements being treated as an admission. Therefore, to aid the review by the Examiner, the applicants will discuss the rejection of the independent claims under 35 U.S.C. §§ 102(e) and 103(a) first, followed by the rejections of the remaining dependent claims under 35 U.S.C. §§ 102(e) and 103(a) second.

Independent Claims:

Independent claims 1, 11, 51, 65 and 73 were rejected under 35 U.S.C. § 102(e) as being anticipated by Gargano et al. 5,814,015. This rejection is respectfully traversed.

Embodiments of the present invention are directed to an external infusion device where the housing is sized to contain at least a portion of a reservoir within the housing. In addition, the drive mechanism is contained within the housing, and the drive mechanism operatively couples with the at least a portion of a reservoir within the housing. Moreover, the housing is sized to fit in a clothing pocket. The Gargano et al. reference, either alone or in combination with any other references, does not disclose, teach or suggest a drive mechanism contained within the housing to couple with at least a portion of a reservoir in the housing, nor is the Gargano et al. device sized to fit in a clothing pocket.

Independent claim 1 as amended now recites “a housing adapted for use on an exterior of the body, wherein the housing is sized to contain at least a portion of a reservoir, wherein the drive mechanism is contained within the housing, wherein the drive mechanism operatively couples with the at least a portion of a reservoir within the housing, and wherein the housing is sized to fit in a clothing pocket” (emphasis added). All of the independent claims 11, 35, 44, 47, 51-55, 65, and 73 have also been amended to recite similar language. The Gargano et al. reference, either alone or in combination with any other references, does not disclose, teach or suggest a drive mechanism contained within the housing to couple with at least a portion of a reservoir in the housing and that is also sized to fit in a clothing pocket, as recited in the claims.

The Gargano et al. reference discloses a hospital pump that sits on an IV pole 14 and is incapable of be worn on the body of a user or having a housing sized to fit in a clothing pocket, as recited in the claims (see Figs. 1-4 and col. 4, lines 9-19). In addition, the Gargano et al. reference does not disclose, teach or suggest a drive mechanism contained within the housing of the device (see Figs. 1-4). Also, the Gargano et al. device does not contain any portion of the multiple syringes in the housing – they are completely external. Moreover, the reservoir does not couple with the drive mechanism within the housing (see Figs. 1-4 and col. 4, lines 9-19). The Gargano et al. device is designed to hold one or more 60 cc syringes (see col. 9, lines 33-36), and is incapable of fitting in a clothing pocket, as recited in the claims.

This failure to meet the limitations was further demonstrated at the interview, when the Gargano et al. device was actually shown to the Examiners. As demonstrated, the displayed device is incapable of being worn on the body and is clearly not sized to fit in a clothing pocket, as recited in the claims. The displayed Gargano et al. device is for sitting on an IV pole in a hospital, weighs over 6 pounds and has dimensions of 10.2” by 8.4 inches by 5.4” without any syringes, IV pole clamp or IV pole attached (as shown on the attached specification sheets A16 and A17 for the Harvard Apparatus). Accordingly, all of the independent claims, 1, 11, 35, 44, 47, 51-55, 65, and 73, are patentably distinguished over the Gargano et al. reference.

Independent claims 1 and 11 are further distinguished by reciting “a housing adapted for

use on an exterior of the body ... wherein the external infusion device is capable of being concealed from view on an individual when being remotely commanded” (emphasis added). The Gargano et al. reference does not disclose, teach or suggest an external infusion device adapted for use on an exterior of the body and which is capable of being concealed from view when being remotely commanded, as recited in the claims.

On page 2, last three lines to page 3, line 3, the Examiner states that the Gargano et al. reference teaches “an indication device ... [to] indicate when the command is being utilized to control the external infusion device such that the external infusion device is capable of being concealed from view on an individual when be remotely commanded, see column 4, line 20 and column 5, lines 49-56” (emphasis added). However, the Gargano et al. device only describes a display at these sections, and there is no disclosure or teaching of any type of concealment (on the body or otherwise) in Gargano et al. reference. The applicants’ fail to comprehend how a display can be used as suggested by the Examiner, when it is concealed from view on an individual when being remotely commanded. Therefore, it is respectfully submitted that the Examiner is engaging in hindsight reconstruction or stretching of the reference without any teaching or suggestion in the Gargano et al. reference to meet the limitations of the claims.

During the interview, the Examiner and her Primary Examiner both argued that is inherent that that one could find some clothing somewhere that could cover an individual and then a pump could be concealed under this very large clothing. This is quite a stretch and ignores the lack of disclosure in the prior art and negates express teachings in the applicant’s own specification where it states that “many users desire to hide the external pump under clothing so as not to seem different from normal people” (see page 2, lines 5-11 and page 12, lines 21-23 of the instant application). The applicants fail to comprehend how the Examiners can credibly support their argument that the patient would then appear no different than normal people, let alone be able to move around easily with a 6+ pound weight of an empty 10.2” by 8.4 inches by 5.4” infusion pump without any syringes, IV pole clamp or IV pole attached. The applicants respectfully submit that there is no support, either through common sense or in the reference, for the Examiner’s position.

Although the applicants agree that inherency is a legally viable method for interpreting a reference (see Verdegaal Bros., Inc. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)), the “examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the applied prior art.” Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Moreover, to serve as an anticipation when the reference is silent about the asserted herein characteristic, such a gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be recognized by persons of ordinary skill. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (emphasis supplied). It is also well settled that inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. Continental Can, 20 USPQ2d at 1749 (emphasis original), quoting In re Oerich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting Hansgirk v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)).

Review of the Gargano et al. reference leads to the inescapable conclusion that there is no reasonable basis to believe that the Gargano et al. reference inherently discloses the external infusion device is capable of being concealed from view on an individual when being remotely commanded,” as recited in claim 1. Because of the nature of the Gargano et al. device, it should be noted that there are definite reasons and teachings away from concealing the Gargano et al. hospital pump regardless of whether or not it is being programmed. For instance, the Gargano et al. device is a hospital pump designed to be held on an IV pole. In this environment, it is supposed to be observable and easily accessible to hospital personnel. Thus, the environment in which the Gargano et al. device is used actually teaches away from the possibility of the Gargano et al. device being concealed on the body of the user and to it being remotely commanded when concealed on the body of the user, as recited in the claims.

In addition, there is no teaching or motivation to conceal the hospital pump from view, when the pump is being programmed. Quite the contrary, a nurse or care giver would want to see the hospital pump as it is being programmed to verify the proper programming and setting of the hospital pump. Also, hospital personnel need to check the hospital pump frequently, and having it concealed, if even possible, would make their rounds more difficult and time consuming. Moreover, a person on a hospital pump of the type disclosed in the Gargano et al. reference is normally in a hospital (or home), and is unlikely to be concerned about appearing different than normal people in the hospital environment. Thus, because the Gargano et al. reference has no disclosure, teaching or suggestion that “the external infusion device is capable of being concealed from view on an individual when being remotely commanded,” the Gargano et al. reference cannot inherently disclose the same.

Finally, the Examiner is reminded that hindsight should be avoided in the analysis of the claims, since “[g]ood ideas may well appear ‘obvious’ after they have been disclosed, despite having been previously unrecognized” Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 43 USPQ2d 1294 (Fed. Cir. 1997). Also, in regard to being capable of concealment or the size of the housing to fit in a clothing pocket, “[c]lose adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one ‘to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against the teacher.’” W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 313. Accordingly, the applicants respectfully submit that there is no support for claims 1 and 11 being anticipated or obvious over the Gargano et al. reference under any acceptable analysis.

Independent claim 11 has been distinguished as discussed above, and is further distinguished by the specific recitation of the wireless remote commander structure and relationship related to the external infusion device. The Gargano et al. reference does not disclose, teach or suggest the remote commander and the relationship to the external infusion device, as recited in claim 11.

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Independent claim 51 is further distinguished over the Gargano et al. reference by reciting “a processor coupled to the housing, a keypad coupled to the housing and used in conjunction with the processor to determine an estimate of remaining battery power, and an indication device to indicate the estimate of remaining battery power” (emphasis added). The Gargano et al. reference does not disclose, teach or suggest the use of a keypad coupled to the housing of the infusion device to determine an estimate of remaining battery power. The Gargano et al. device has no keypad – at best only knobs 30, 32, 36 and 38. The Gargano et al. reference does not teach or suggest a device to estimate the remaining battery power, nor does it teach or suggest an indication device to indicate the estimate of the remaining battery power, as recited in claim 51. The Gargano et al. does teach a low battery alarm, but not an estimate of remaining battery power.

Independent claim 65 is further distinguished from the Gargano et al. reference by reciting “a vibration alarm used in conjunction with the processor to provide one or more tactile sensations to the user” (emphasis added). The Examiner has failed to cite any portion of the Gargano et al. reference that discloses, teaches or suggests a vibration alarm to provide one or more tactile sensations to the user. The Gargano et al. reference contains no description of a vibration device. In fact, the sections of the Gargano et al. reference cited by the Examiner make no mention of the use of vibrations, and does not teach or suggest the use of a vibration alarm, as recited in the claim 65. In addition, it is noted that a vibration alarm on a hospital pump that sits on an independent and free-standing IV pole is unlikely to be effective

Moreover, regarding claim 65, the Examiner asserted in the Office Action that an audio alarm is considered to be a vibration alarm (see page 3, last paragraph of the instant Office Action). This is inconsistent with the customary usage of the term in various industries. Although both alarms utilize waves (sound or shaking), those of ordinary skill in the art clearly realize that a vibration alarm is not the equivalent of an audio alarm. The primary objective of one alarm is to provide a tactile sensation and the other is to provide a sound. For instance, although in a non-analogous field, manufacturers of pagers and cellular telephone consistently provide a vibration alert that is different from the audible ring. The user can select a particular

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one based on the environment they will be in. The Examiner has provided no reference or art that supports the argument that a vibration alarm is the same as an audio alarm. If the Examiner has such a reference, the Examiner should provide it and quote the relevant sections.

Therefore, it is respectfully submitted that the rejection of independent claims 1, 11, 51, 65 and 73 under 35 U.S.C. § 102(e) by the Gargano et al. reference should be withdrawn.

Independent claims 35, and 52-55 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by Gargano et al. 5,814,015 in view of DeCant, Jr. et al. 4,443,218. This rejection is respectfully traversed.

As admitted by the Examiner, the Gargano et al. reference does not disclose, teach or suggest any type of bolus estimator. In addition, claim 35 has also been distinguished over the Gargano et al. reference with the same limitations added to claims 1 and 11 discussed above.

The DeCant, Jr. et al. reference does not make up for the deficiencies of the Gargano et al. reference. The Examiner has cited no portion of the DeCant, Jr. et al. reference that in any manner teaches or suggests the embodiments recited in claims 35-43. For example, independent claim 35 recites an “external infusion device for infusion of a liquid into a body, the external infusion device comprising: ... a processor coupled to the housing, a bolus estimator used in conjunction with the processor and externally supplied values to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body; and an indication device to indicate when an amount of fluid to be infused has been calculated” (emphasis added). The DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device that includes a bolus estimator used with a processor and external values to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body. Thus, the DeCant, Jr. et al. reference does not disclose, teach or suggest a bolus estimator that provides an estimate of ingested material, as recited in claim 35.

The DeCant, Jr. et al. reference discloses and implantable pump with the ability to switch

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between two delivery rates. The DeCant, Jr. et al. reference does describe that the patient can tailor the bolus rate to match the characteristics of the meal, as shown at col. 2, lines 39-42. However, it is clear from the description at col. 5, lines 55-59 and col. 8, lines 47-48 and 53-63 that this accomplished solely by the use of a switch 96, or a limited patient programmer, that lets the patient only switch between a basal flow rate and a higher bolus flow rate (see col. 8, line 64 to col. 9, line 17). Thus, the patient must manually switch or command the implantable pump to change flow rates to deliver a desired bolus amount. There is no disclosure, teaching or suggestion anywhere in the DeCant, Jr. et al. reference of the implantable pump actually calculating the duration of or the size of the bolus delivery. It is all up to the patient to determine by approximation or determination without the aid any feature contained in the implantable pump. Also, there is no disclosure, teaching or suggestion of the implantable pump providing an estimate or how an estimate from an internal implantable infusion pump could be made available to a user.

Conversely, the claimed bolus estimator uses the processor (either as part of the processor or as a separate element) and externally supplied values to estimate the amount of liquid to be infused. Thus, the patient need not guess how much fluid is needed, the external infusion device performs the calculation and provides that information to the patient. Therefore, the teaching of DeCant, Jr. et al. implantable pump is fundamentally different, since it requires the patient to determine when to start and end the bolus rate, while the claimed bolus estimator determines an estimate based on various values supplied to the external infusion device and informs the patient of an estimate of an amount of fluid to be infused.

During the discussions in the various interviews, the Examiner stated the bolus estimator is essentially a calculator and that any processor could do the calculations. The applicants do not assert that a calculator or a processor could not do calculations similar to the bolus estimator. However, the Examiner has not cited a single patent reference that includes the bolus estimator within the infusion device in combination with the other elements of the infusion device. In addition, the Examiner has not cited a single reference where the user inputs values representing an amount of material to be ingested and then the estimator uses that value to come up with an

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estimate of an amount of fluid to be infused to compensate for the amount of material ingested fluid. The Examiner has also not shown any calculator or processor reference that also includes some teaching or suggestion to modify the calculator or processor to be included in an infusion device or the desirability to do so.

Moreover, it is respectfully submitted that it would not have been obvious to combine the Gargano et al. and De Cant, Jr. et al. references, as suggested by the Examiner. It is well settled that a reference must provide some motivation or reason for one skilled in the art (working without the benefit of the applicants' specification) to make the necessary changes in the disclosed device. The mere fact that a reference may be modified in the direction of the claimed invention does not make the modification obvious unless the reference expressly or impliedly teaches or suggests the desirability of the modification. In re Gordon, 221 USPQ 1125, 1127 (Fed. Cir. 1984); Ex parte Clapp, 227 USPQ 972, 973 (Bd. App. 1985); Ex parte Chicago Rawhide Mfg. Co., 223 USPQ 351, 353 (Bd. App. 1984).

The cited references, Gargano et al. and De Cant, Jr. et al., fail to meet the basic requirement for a finding of obviousness established by the courts in Gordon, Clapp, and Chicago Rawhide. There is no suggestion in any of the references of modifying the devices disclosed therein in the direction of the present invention, nor is there any suggestion whatsoever of the desirability of such modification (i.e., of a taking a hospital pump and combining it with an implantable pump that can switch between a basal rate and a bolus rate to yield an external infusion device including a bolus estimator that uses the input of material to be ingested to determine an estimate of the amount of liquid to be infused). Thus, it is respectfully submitted that the ordinarily skilled artisan would have no motivation to combine the references as suggested by the Examiner.

The Examiner has failed to cite any disclosure or suggestion of a bolus estimator in an external infusion device that uses the input of material to be ingested to determine an estimate of the amount of liquid to be infused. Instead, the Examiner has made statements that the switching between rates, without any input of values or outputting an estimate is the same. These

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statements are not supported by the references and do not reflect what is recited in the claims. Also, without the teaching or suggestion of a bolus estimator in an external infusion device that uses the input of material to be ingested to determine an estimate of the amount of liquid to be infused, it is respectfully submitted that the Examiner is engaging in hindsight reconstruction of the claimed invention. For example, as previously pointed out, the Examiner is using the claimed invention as a template to take a hospital pump and combining it with an implantable pump that can switch between a basal rate and a bolus rate to yield an external infusion device including a bolus estimator that uses the input of material to be ingested to determine an estimate of the amount of liquid to be infused. The Examiner takes this position even though the Examiner has not cited a single reference that discloses, teaches or suggests a bolus estimator in an external infusion device that uses the input of material to be ingested to determine an estimate of the amount of liquid to be infused.

As discussed above, the U.S. Court of Appeals for the Federal Circuit has provided an analytical approach for assessing the obviousness issue. The Examiner has not followed this approach and has failed to establish a case of obviousness. Applicants respectfully submit that such a case cannot be established. Therefore, the rejection of claims 35-43 under 35 U.S.C. § 103 over the Gargano et al. reference in view of the DeCant, Jr. et al. should be withdrawn, and the claims found allowable over the art of record.

Independent claims 52 and 53 have been distinguished over the Gargano et al. reference with the same limitations added to claims 1 and 11 discussed above. The DeCant, Jr. et al. reference does not make up for the deficiencies of the Gargano et al. reference. Claims 52 and 53 are further distinguished by reciting an "external infusion device comprising: ... a processor coupled to the housing, ... a memory coupled to and used in conjunction with the processor to store at least two personal delivery patterns, ... an indication device to indicate the selected personal delivery pattern, wherein the processor controls the external infusion device in accordance with the selected one of the at least two personal delivery patterns" (emphasis added). Neither, the Gargano et al. reference nor the DeCant, Jr. et al. reference teaches or suggests an external infusion device or a memory to store at least two personal delivery patterns, as recited in

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the claims. Thus, values for only one set of parameters are stored for the single flow rate pattern used by the patient, and the Gargano et al. reference and DeCant, Jr. et al. reference do not teach or suggest a memory to store at least two personal delivery patterns, as recited in claims 52 and 53.

In addition, the ability to switch between bolus and basal rates is not the same as the at least two personal delivery patterns recited in the claims. There is no pattern, since one merely switches between two different rates. Furthermore, the DeCant, Jr. et al. patient external programmer is not disclosed as including an indication device, as recited in the claims. Moreover, there is no disclosure, teaching or suggestion of at least two delivery patterns being stored in the memory of an implantable pump.

Independent claim 54 has been distinguished over the Gargano et al. reference with the same limitations added to claims 1 and 11 discussed above. The DeCant, Jr. et al. reference does not make up for the deficiencies of the Gargano et al. reference. Claim 54 is further distinguished by reciting an “external infusion device for infusion of a liquid into a body, the external infusion device comprising:...a memory coupled to and used in conjunction with the processor to store at least two basal rate profiles, a keypad coupled to the housing and used in conjunction with the processor to program the at least two basal rate profiles, and an indication device to indicate the basal rate profiles during programming, wherein the processor controls the external infusion device in accordance with the programmed at least two basal rate profiles” (emphasis added). The Gargano et al and DeCant, Jr. et al. references only describe and disclose storing basal and bolus rates in the memory of the pump. Thus, the Gargano et al. and DeCant, Jr. et al. references do not disclose, teach or suggest an external infusion device including a memory to store at least two basal rate profiles, as recited in claim 54.

In addition, the ability to switch between bolus and basal rates is not the same as the at least two basal profiles recited in the claims. There is no profile, since one merely switches between two different rates. Furthermore, the DeCant, Jr. et al. patient external programmer is not disclosed as including an indication device, as recited in the claims. Moreover, there is no

disclosure, teaching or suggestion of at least two basal profiles being stored in the memory of the pump.

Independent claim 55 has been distinguished over the Gargano et al. reference with the same limitations added to claims 1 and 11 discussed above. The DeCant, Jr. et al. reference does not make up for the deficiencies of the Gargano et al. reference. Claim 55 is further distinguished by reciting an “external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing, a processor coupled to the housing, a memory coupled to and used in conjunction with the processor to store at least two bolus types, a keypad coupled to the housing and used in conjunction with the processor to select one of the at least two bolus types, and an indication device to indicate the selected bolus type, wherein the processor controls the external infusion device in accordance with the selected one of the at least two bolus types” (emphasis added). The Gargano et al. and DeCant, Jr. et al. references only describe and disclose a single bolus rate or maximum amounts that are stored in the memory of the pump. Thus, the Gargano et al. and DeCant, Jr. et al. references do not disclose, teach or suggest an external infusion device including a memory to store at least two bolus types, as recited in claim 55.

In addition, the ability to switch between bolus and basal rates is not the same as the at least two bolus types recited in the claims. There is no pattern, since one merely switches between two different rates. Furthermore, the DeCant, Jr. et al. patient external programmer is not disclosed as including an indication device, as recited in the claims. Moreover, there is no disclosure, teaching or suggestion of at least two bolus types being stored in the memory of the implantable pump.

Therefore, it is respectfully submitted that the rejection of independent claims 35 and 52-55 under 35 U.S.C. § 103(a) by the Gargano et al. in view of DeCant, Jr. et al. reference should be withdrawn.

Independent and Dependent Claims:

Claims 44-50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by Gargano et al. 5,814,015 in view of Dent, 5,609,060. This rejection is respectfully traversed.

Claims 44-50 are further distinguished over the Gargano et al. reference by claiming unique applications or uses for the vibration alarm. Claims 44-46 state that the vibration alarm is used to, “remove gas bubbles from the fluid in the reservoir during priming,” “agitate fluid in the reservoir between successive delivery periods,” or “agitate the fluid in the reservoir during delivery,” respectively. Claims 48 and 49 recite similar language. Claim 47 recites, “a vibration alarm used in conjunction with the processor and the audible alarm.” And claim 50 recites that, “the processor selects to activate one of the audible alarm and vibration alarm independently.” The Gargano et al. reference does not disclose, teach, or suggest uses for a vibration alarm alone, or in conjunction with an audible alarm, as recited in claims 44-50.

The Dent reference does not make up for the deficiencies of the Gargano et al. reference. The Dent reference is directed to a multiple channel manometer apparatus to provide information regarding the function of the digestive tract in animals and children. The device uses water and carbon dioxide. This is an external type of pump, but it is not capable of being concealed. There is also no teaching or suggestion that the disclosed techniques could be applied to implantable pumps or devices concealed on the body. In addition, the Dent reference does not disclose, teach or suggest external infusion devices or how features from implantable pumps could be applied to external infusion devices, as recited in the claims.

Therefore, it is respectfully submitted that the rejection of claims 44-50 under 35 U.S.C. § 103(a) by the Gargano et al. reference and the Dent reference should be withdrawn.

New Dependent Claims:

New dependent claims 74-146 have been added to the application. No new matter has been added. The applicants a series of new dependent claims (74-145) for each pending independent claim to further clarify the newly added limitation of “sized to fit in a clothing pocket.” The purpose is to show that the external infusion device is sized to fit in a pocket, but

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does not need to be in a pocket to operate or be used. Also, the limitations on the housing, added to the independent claims, should not be read as to exclude external infusion devices that utilize needles, tubes, catheters, cannulas, infusion sets, and/or the like to deliver a liquid to a body, or that can be worn on belts, under clothing, or against or on the skin of a patient. Claim 146 recites “wherein the receiver receives wireless and remotely generated commands, wherein the process or receives the wireless and remotely generated commands from the receiver, and wherein the processor controls the external infusion device in accordance with the wireless and remotely generated commands.” The Examiner indicated that this limitation would clearly be allowable over the new identified (but not disclosed) reference. Accordingly, it is respectfully submitted that new dependent claims 74-146 are in condition for allowance.

Rejected Dependent Claims:

Dependent claims 2-10, 12, 13, 20-34, 56, 57 and 66-69 were rejected under 35 U.S.C. § 102(e) as being anticipated by Gargano et al. 5,814,015. This rejection is respectfully traversed.

Dependent claims 2-10, 12, 13, 20-34, 56, 57 and 66-69 depend from claims 1, 11 and 65, which as discussed above is patentably distinguished over the Gargano et al. reference. Therefore, dependent claims 2-10, 12, 13, 20-34, 56, 57 and 66-69 are also patentably distinguished over the Gargano et al. reference for the same reasons.

Dependent claim 3 is further distinguished from the Gargano et al. reference by reciting “wherein the external infusion device includes a memory for storing a patient infusion history and pump activity” (emphasis added). The Gargano et al. reference does not disclose, teach or suggest a memory for storing a patient infusion history in an external infusion device, as recited in claim 3. The section cited by the Examiner is for defining patient parameters prior to infusion and makes no mention of using this memory for storing a patient infusion history, as recited in the claim.

Dependent claims 4, 28 and 56 are further distinguished from the Gargano et al. reference by reciting “wherein the remotely generated commands are capable of programming and

activating an audio bolus delivery of the liquid by the external infusion device” (emphasis added). The Examiner has cited no portion of the Gargano et al. reference that discloses, teaches or suggests a device where the remotely generated commands are capable of programming and activating an audio bolus delivery of the liquid by the external infusion device, as recited in claims 4, 28 and 56. In fact, the sections of the Gargano et al. reference cited by the Examiner make no mention of the use of audio. There is no teaching or suggestion in the Gargano et al. reference of an audio device being used in conjunction with the administration of a bolus, as recited in the claims 4, 28 and 56.

Dependent claims 5, 29, and 57 are further distinguished from the Gargano et al. reference by reciting “the remotely generated commands are capable of programming and activating a vibration bolus delivery of the liquid by the external infusion device” (emphasis added). The Examiner has failed to cite any portion of the Gargano et al. reference that discloses, teaches or suggests a vibration bolus. The Gargano et al. reference contains no description of a vibration device. In fact, the sections of the Gargano et al. reference cited by the Examiner make no mention of the use of vibrations. Furthermore, the Gargano et al. reference does not teach or suggest the use of a vibration device in conjunction with a bolus delivery, as recited in the claims 5, 29 and 57. In addition, it is noted that a vibration alarm on a hospital pump that sits on an independent and free-standing IV pole is unlikely to be effective

Moreover, regarding Dependent claims 5, 29, 57 and 66-69, the Examiner asserted in the Office Action that an audio alarm is considered to be a vibration alarm (see page 3, last paragraph of the instant Office Action). This is inconsistent with the customary usage of the term in various industries. Although both alarms utilize waves (sound or shaking), those of ordinary skill in the art clearly realize that a vibration alarm is not the equivalent of an audio alarm. The primary objective of one alarm is to provide a tactile sensation and the other is to provide a sound. For instance, although in a non-analogous field, manufacturers of pagers and cellular telephone consistently provide a vibration alert that is different from the audible ring. The user can select a particular one based on the environment they will be in. The Examiner has provided no reference or art that supports the argument that a vibration alarm is the same as an

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audio alarm. If the Examiner has such a reference, the Examiner should provide it and quote the relevant sections.

Dependent claims 6 and 30 are further distinguished from the Gargano et al. reference by reciting “wherein the remotely generated commands are capable of programming and activating a temporary basal rate delivery of the liquid by the external infusion device” (emphasis added). Although the Gargano et al. reference does describe a basal flow and setting parameters for the basal flow, it does not disclose, teach or suggest multiple basal rates or the ability to program and activate a temporary basal rate. Also, the Gargano et al. reference contains no description of a temporary basal rate. In fact, the sections of the Gargano et al. reference cited by the Examiner make no mention of the use of temporary basal rates.

Dependent claims 7 and 31 are further distinguished from the Gargano et al. reference by reciting “wherein the remotely generated commands are capable of programming and suspending delivery of the liquid by the external infusion device.” The Gargano et al. reference does not disclose, teach or suggest an external infusion device with remote programming to suspend delivery of the liquid, as recited in claims 7 and 31. The only suspension described in the cited section is by direct intervention on the Gargano et al. device.

Dependent claims 8 and 32 are further distinguished from the Gargano et al. reference by reciting “wherein the remotely generated commands are capable of programming and activating an extended bolus delivery of the liquid by the external infusion device” (emphasis added). The Gargano et al. reference does disclose switching to a bolus flow rate, but this does not equate to programming and activating an extended bolus. The Examiner has failed to cite any portion of the Gargano et al. reference that discloses, teaches or suggests an extended bolus. Also, the Gargano et al. reference contains no description of an extended bolus.

Dependent claims 9 and 34 are further distinguished from the Gargano et al. reference by reciting “the remotely generated commands are capable of programming and activating a dual wave bolus delivery of the liquid by the external infusion device” (emphasis added). The

Examiner has cited no portion of the Gargano et al. reference that discloses, teaches or suggests a dual wave bolus delivery of liquid. Also, the Gargano et al. reference contains no description of a dual wave bolus. In fact, the sections of the Gargano et al. reference cited by the Examiner make no mention of the use of a dual wave bolus, as recited in claims 9 and 34.

Dependent claims 10 and 33 are further distinguished from the Gargano et al. reference by reciting “wherein the remotely generated commands are capable of programming and activating a profiled bolus delivery of the liquid by the external infusion device” (emphasis added). The Gargano et al. reference does disclose switching to a bolus flow rate, but it does not disclose, teach or suggest that this bolus can be profiled in any manner. The Examiner has failed to cite any portion of the Gargano et al. reference that discloses, teaches or suggests a profiled bolus. Also, the Gargano et al. reference contains no description of a profiled bolus.

Dependent claim 12 is further distinguished from the Gargano et al. reference by reciting “wherein the external infusion device further includes a device transmitter to verify receipt of commands from the remote commander, wherein the remote commander further includes a remote receiver to receive the verification from the device transmitter of the external infusion device, and wherein the remote commander further includes a remote indication device to indicate receipt of the verification from the external infusion device. The Examiner has failed to cite any portion of the Gargano et al. reference that discloses, teaches or suggests an external infusion device with a transmitter for communicating with a programmer having a receiver and an indication device. Also, the Gargano et al. reference contains no description of an external infusion device with a transmitter for communicating with a programmer having a receiver and an indication device. The Gargano et al. reference only describes a wired connection to a computer, or other host device (see col. 20, lines 23-36). In fact, the sections of the Gargano et al. reference cited by the Examiner make no mention of the use of an external infusion device with a transmitter for communicating with a programmer having a receiver and an indication device.

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Dependent claim 13 is further distinguished by reciting the remote commander is sized to fit a key ring. The Gargano et al. reference only mentions computers, and other host device, with a wired connection as being suitable for programming the Gargano et al. hospital pump. However, there is no disclosure, teaching or suggestion of the computer, or other host device, being sized to fit on a key ring.

Dependent claim 20 is further distinguished from the Gargano et al. reference by reciting “wherein the remote commander is capable of providing remote commands at a distance greater than 1 inch.” The Examiner has cited no portion of the Gargano et al. reference that discloses, teaches or suggests that a wireless programmer can provide wireless commands at a distance greater than 1 inch.

The Examiner rejected dependent claims 21-22 by simply reciting back the limitations in the claims without a specific reference to where it is disclosed in the Gargano et al. reference. Claim 21 is further distinguished from the Gargano et al. reference by reciting “wherein the processor of the external infusion device has a unique identification code, and wherein the remote commander includes the capability to read and learn the unique identification code of the external infusion device, and wherein the remote commander and the external infusion device use the unique identification code to substantially avoid interference with other external infusion devices,” (emphasis added), and claim 22 similarly recites, “wherein the remote commander has a unique identification code, and wherein the processor of the external infusion device includes the capability to read and learn the unique identification code of the remote commander, and wherein the remote commander and the external infusion device use the unique identification code to substantially avoid interference with other remote commanders” (emphasis added). The Examiner has cited no portion of the Gargano et al. reference that discloses, teaches or suggests an external infusion device that has a unique identification code that can be read by a remote commander, or a remote commander that has a unique identification code that can be read by an external infusion device, as recited in the claims. The Gargano et al. reference does not disclose, teach or suggest the additional feature of an identification code to prevent interference in any of its embodiments. In fact, due to the Gargano et al. device’s wired connection to a PC, this

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feature would be unnecessary, and it could be argued that the Gargano et al. reference teaches away from these features recited in the claims.

Dependent claim 23 is further distinguished from the Gargano et al. reference by reciting “wherein the remote commander includes a mode that permits physician controlled programming of specific capabilities of the external infusion device to the exclusion of the user.” The Gargano et al. device does disclose a software lockout on the infusion device itself. However, the Gargano et al. reference does not disclose, teach or suggest a remote commander that includes a mode that permits the exclusion of the user, as recited in the claim.

Dependent claims 26 and 27 are further distinguished over the Gargano et al. reference by reciting “wherein the remote commander is capable of receiving data from another medical device and relaying the received data to the external infusion device,” and furthermore, “the remote commander is capable of remotely commanding and controlling the other medical device.” The Examiner has cited no portion of the Gargano et al. reference, which teaches or suggests a remote commander capable of receiving data from another medical device and relaying the data to the external infusion device, as recited in claim 26. Nor has the Examiner cited a portion of the Gargano et al. reference, which further teaches or suggests a remote commander that could also remotely command and control the other medical device, as recited in the claims. The Gargano et al. reference does not teach or suggest the additional feature of a device that is capable of programming an external infusion device and also communicating with and/or commanding and controlling another device, as recited in claims 26 and 27.

Therefore, it is respectfully submitted that the rejection of dependent claims 2-10, 12, 13, 20-34, 56, 57 and 66-69 under 35 U.S.C. § 102(e) by the Gargano et al. reference should be withdrawn.

Dependent claims 36-43, 58-64 and 70-72 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by Gargano et al. 5,814,015 in view of DeCant, Jr. et al. 4,443,218. This rejection is respectfully traversed.

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Dependent claims 36-43, 58-64 and 70-72 depend from claims 11, 35 and 52, which as discussed above is patentably distinguished over the Gargano et al. and DeCant, Jr. et al. references. Therefore, dependent claims 2-10, 12, 13, 20-34, 56, 57 and 66-69 are also patentably distinguished over the Gargano et al. and DeCant, Jr. et al. references for the same reasons.

Dependent claims 36, 37, and 40 are further distinguished from the Gargano et al. and DeCant, Jr. et al. references by reciting specific additional features of the bolus estimator that are not disclosed, taught, or suggested in the DeCant, Jr. et al. reference. The Examiner has cited, no portion of the DeCant, Jr. et al. reference that teaches or suggests an external infusion device with a bolus estimator that includes “the capability to calculate a correction bolus based upon a current characteristic value and a target characteristic value,” as recited in claim 36, or “a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus,” as recited in claim 37, or “a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus is estimated by the bolus estimator,” as recited in claim 40. The Examiner makes broad statements that these elements are disclosed in the DeCant, Jr. et al. reference, but this is simply not the case and the sections specifically cited by the Examiner do not contain any language that could be construed to cover these elements. If the Examiner believes that these elements are described in the DeCant, Jr. et al. reference, the Examiner should quote the specific language that supports, shows and meets the limitations in the claims. The applicants respectfully submit that this is simply not possible.

Dependent claims 38 and 39 are further distinguished over the Gargano et al. and DeCant, Jr. et al. references by reciting “the liquid to be infused is insulin” and “where the material to be ingested is carbohydrates,” respectively. While the DeCant, Jr. et al. implantable pump may be used for insulin pumps, there is no teaching or suggestion in the DeCant, Jr. et al. reference of the additional feature of a device to estimate an amount of insulin to be infused based upon an estimate of carbohydrates to be ingested by the body, as recited in claims 38 and 39.

Dependent claims 41 and 42 are further distinguished over the Gargano et al. and DeCant,

Jr. et al. references by reciting that the supplied values used in conjunction with the a bolus estimator and the processor are “codes representing a carbohydrate value of specific foods” or “codes representing a carbohydrate value of specific meals,” respectively. The DeCant, Jr. et al. reference does not teach or suggest the additional feature of a device with a bolus estimator that accepts codes representing a carbohydrate value of foods or meals, as recited in claims 41 and 42.

Dependent claim 43 is further distinguished over the Gargano et al. and DeCant, Jr. et al. references by reciting that the external infusion device further includes “a duration factor to determine a value of how long a previously infused amount of liquid will remain active in the body, wherein the determined value is used to adjust the amount of the fluid to be infused” (emphasis added). Thus, the Examiner has cited no portion of the DeCant, Jr. et al. reference that teaches or suggests the additional feature of a duration factor to adjust the amount of the fluid to be infused.

Dependent claim 58 is further distinguished by reciting an infusion system comprising, “a remote commander including...a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device, wherein the remote commander is portable,” (emphasis added). The Gargano et al. reference does not disclose, teach or suggest an external infusion system with a remote commander that has a transmitter for wirelessly transmitting commands to the receiver of the external infusion device, and where the remote commander is portable.

Dependent claim 59 is further distinguished by reciting an infusion system comprising a remote commander “wherein the remote commander is one or more remote commanders and each of the one or more remote commanders includes: a commander housing, a keypad coupled to the commander housing for inputting commands, and a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device” (emphasis added). The Gargano et al. reference does not disclose, teach or suggest a wireless commander or an external infusion device with one or more remote programmers, as recited in claim 59.

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Dependent claim 60 is further distinguished by reciting “wherein the one or more remote commanders each have a unique identification code, and wherein the processor of the external infusion device includes the capability to store the unique identification codes of the one or more remote commanders, and wherein the one or more remote commanders and the external infusion device use the unique identification codes to substantially avoid interference with other remote commanders” (emphasis added). The Gargano et al. reference does not disclose, teach or suggest the use of remote commanders each with a unique identification code that the external infusion device stores and uses to substantially avoid interference with other remote commanders. The Gargano et al. reference does not teach or suggest that access codes may be used in any way to avoid interference with other remote commanders. The Gargano et al. reference only described a wired connection to a computer, or other host device (see col. 20, lines 23-36). In fact, the sections of the Gargano et al. reference cited by the Examiner make no mention of the use of an external infusion device with a transmitter for communicating with a programmer having a receiver and an indication device, as recited in claim 60.

Dependent claim 61 is further distinguished by reciting “wherein the external infusion device is programmable to store one or more identification codes, wherein each remote commander transmits an identification code, and wherein the external infusion device only responds to commands sent from a remote commander that transmits an identification code that has been programmed into the external infusion device” (emphasis added). The Gargano et al. reference does not disclose, teach or suggest an external infusion device that is programmable to store one or more identification codes and will only respond to commands sent from a remote commander that transmits an identification code that has been programmed, as recited in claim 61. The Gargano et al. reference only described a wired connection to a computer, or other host device (see col. 20, lines 23-36). In fact, due to the Gargano et al. device’s wired connection to a PC, this feature would be unnecessary, and it could be argued that the Gargano et al. reference teaches away from these features recited in the claims.

Dependent claim 62 is further distinguished by reciting “wherein the remote commander establishes non-line of sight communication with the external infusion device.” Since the

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Gargano et al. reference discloses, teaches or suggest an external infusion device with a wired connection, it does not disclose, teach or suggest an external infusion device with a remote commander that establishes non-line of sight communication with the external infusion device as recited in claim 62.

Dependent claim 63 is further distinguished by reciting an external infusion device including a receiver for receiving remotely generated commands “wherein the receiver includes a standby mode, and wherein while the receiver is in the standby mode the receiver does not receive.” Since the Gargano et al. reference discloses, teaches or suggests an external infusion device with a wired connection, it does not disclose, teach or suggest an external infusion device with a receiver that does not receive while in a standby mode, as recited in claim 63.

Dependent claim 64 is further distinguished by reciting an external infusion device including a receiver for receiving remotely generated commands, ... wherein while the receiver is in the standby mode the receiver does not receive and, “wherein the receiver periodically becomes active to see if the transmitter is transmitting” (emphasis added.). Since the Gargano et al. reference discloses, teaches or suggests an external infusion device with a wired connection, it does not disclose, teach or suggest an external infusion device with a receiver that periodically becomes active to see if a transmitter is transmitting, as recited in claim 64.

Dependent claim 70 is further distinguished by reciting an external infusion device including a processor to store at least two personal delivery patterns “wherein the at least two personal delivery patterns are programmable by a user,” (emphasis added). As discussed previously, the Gargano et al. reference does not teach or suggest a memory to store at least two personal delivery patterns, as recited in the claims. The Gargano et al. reference does not teach or suggest a memory to store at least two personal delivery patterns, as recited in the claims. Thus, values for only one set of parameters are stored for the single flow rate pattern used by the patient, and the Gargano et al. reference does not teach or suggest a memory to store at least two personal delivery patterns, as recited in claim 70.

Dependent claims 71 and 72 were not rejected in the present Office Action. Claims 71 and 72 are distinguished over the Gargano et al. and DeCant, Jr. et al. references, by virtue of arguments presented earlier that the Gargano et al. and DeCant, Jr. et al. references, do not teach or suggest the use of two or more personal delivery patterns. Claims 71 and 72 serve to further define embodiments of the present invention. The applicants respectfully submit that claims 71 and 72 do not read on the Gargano et al. and DeCant, Jr. et al. references and are in condition for allowance.

Therefore, it is respectfully submitted that the rejection of dependent claims 36-43, 58-64 and 70-72 under 35 U.S.C. § 103(a) by the Gargano et al. in view of DeCant, Jr. et al. reference should be withdrawn.

Claims 14 and 16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by Gargano et al. 5,814,015 in view of Bentsen et al. 6,009,339. This rejection is respectfully traversed.

Claims 14 and 16 depend from claim 11, which as discussed above is patentably distinguished over the Gargano et al. reference. Therefore, claims 14 and 16 are also patentably distinguished over the Gargano et al. reference for the same reasons.

The Bentsen et al. reference does not make up for the deficiencies of the Gargano et al. reference. The Bentsen et al. reference is directed to a blood parameter measuring device and does not disclose, teach or suggest external infusion devices or how features from implantable pumps could be applied to external infusion devices, as recited in the claims.

Therefore, it is respectfully submitted that the rejection of claims 14 and 16 under 35 U.S.C. § 103(a) by the Gargano et al. reference and the Bentsen reference should be withdrawn.

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over by Gargano et al. 5,814,015 in view of Dempsey et al, 5,687,734. This rejection is respectfully traversed.

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Claim 15 depends from claim 11, which as discussed above is patentably distinguished over the Gargano et al. reference. Therefore, claim 15 is also patentably distinguished over the Gargano et al. reference for the same reasons.

The Dempsey et al. reference does not make up for the deficiencies of the Gargano et al. reference. The Dempsey et al. reference is directed to a patient monitoring system for a telemetry network in a hospital and does not disclose, teach or suggest external infusion devices or how features from implantable pumps could be applied to external infusion devices, as recited in the claims.

Claim 15 is further distinguished over the Gargano et al. reference and the Dempsey et al. reference by reciting "wherein the remote commander uses IR frequencies to transmit remote commands to the external infusion device." Since the Gargano et al. reference and the Dempsey et al. reference do not disclose, teach or suggest an external infusion device, they do not disclose, teach or suggest an external infusion device with remote programmer that uses IR frequencies, as recited in claim 15. In addition, since the Gargano et al. implantable pump is implanted under the skin of the user, IR frequencies will not work and the Gargano et al. reference actually teaches away from the use of IR frequencies.

Therefore, it is respectfully submitted that the rejection of claim 15 under 35 U.S.C. § 103(a) by the Gargano et al. reference and the Dempsey et al. reference should be withdrawn.

Claims 17 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by Gargano et al. 5,814,015 in view of Feierbach 5,861,018. This rejection is respectfully traversed.

Claims 17 and 18 depend from claim 11, which as discussed above is patentably distinguished over the Gargano et al. reference. Therefore, claims 17 and 18 are also patentably distinguished over the Gargano et al. reference for the same reasons.

The Feierbach reference does not make up for the deficiencies of the Gargano et al. reference. The Feierbach reference is directed to an external transdermal communication device that communicates with an implanted medical communication device and does not disclose, teach or suggest external infusion devices or how features from implantable pumps could be applied to external infusion devices, as recited in the claims.

Claim 17 is further distinguished over the Gargano et al. reference and the Feierbach reference by reciting “wherein the remote commander uses ultrasonic frequencies to transmit remote commands to the external infusion device.” Since the Gargano et al. reference and the Feierbach do not disclose, teach or suggest an external infusion device, they do not disclose, teach or suggest an external infusion device with a remote programmer that uses ultrasonic frequencies, as recited in claim 17.

Claim 18 is further distinguished over the Gargano et al. reference and the Feierbach reference by reciting “wherein the remote commander uses audio frequencies to transmit remote commands to the external infusion device.” Since the Gargano et al. reference and the Feierbach reference do not disclose, teach or suggest an external infusion device, they do not disclose, teach or suggest an external infusion device with a remote programmer that uses ultrasonic frequencies, as recited in claim 18.

Therefore, it is respectfully submitted that the rejection of claims 17 and 18 under 35 U.S.C. § 103(a) by the Gargano et al. reference and the Feierbach reference should be withdrawn.

Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over by Gargano et al. 5,814,015 in view of Batina et al. 4,550,731. This rejection is respectfully traversed.

Claim 19 depends from claim 11, which as discussed above is patentably distinguished over the Gargano et al. reference. Therefore, claim 19 is also patentably distinguished over the Gargano et al. reference for the same reasons.

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The Batina et al. reference does not make up for the deficiencies of the Gargano et al. reference. The Batina et al. reference is directed to a communication device for an implanted cardiac pacemaker and does not disclose, teach or suggest external infusion devices or how features from implantable pumps could be applied to external infusion devices, as recited in the claims.

Claim 19 is further distinguished over the Gargano et al. reference and the Batina et al. reference by reciting “wherein the remote commander uses magnetic effects to transmit remote commands to the external infusion device.” Since the Gargano et al. reference and the Batina et al. reference do not disclose, teach or suggest an external infusion device, they do not disclose, teach or suggest an external infusion device with a remote programmer that uses magnetic effects, as recited in claim 19.

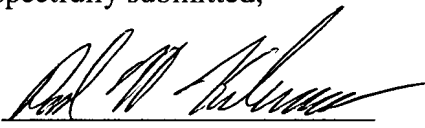
Therefore, it is respectfully submitted that the rejection of claim 19 under 35 U.S.C. § 103(a) by the Gargano et al. reference and the Batina et al. reference should be withdrawn.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned attorney at (818) 576-5313 should the Examiner believe a telephone interview would advance the prosecution of the application.

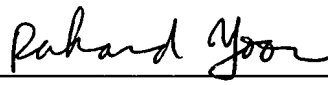
Respectfully submitted,

Dated: May 13, 2002

By:   
Paul H. Kovelman  
Reg. No.: 35,228

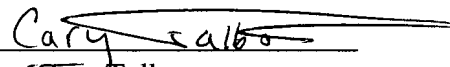
Respectfully submitted,

Dated: May 13, 2002

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